



Medical Necessity Criteria for Drug Class: Calcium Channel Blockers

Background

The Calcium Channel Blockers drug class includes dihydropyridines (CCBs-DHP) and diltiazem and verapamil (non-dihydropyridines). After evaluating the relative clinical and cost effectiveness of the dihydropyridine calcium channel blockers, the DoD P&T Committee recommended that the following medications be designated as non-formulary:

- **CCBs-DHP** – Sular geomatrix, Cardene SR, DynaCirc, DynaCirc CR, nifedipine immediate release
- **Verapamil products** - Verelan, Verelan PM, Covera HS
- **Diltiazem products** - Cardizem LA

This recommendation has been approved by the Director, TMA.

Effective Date: 7 January 2009

Patients currently using a nonformulary CCB may wish to ask their doctor to consider a formulary alternative

Special Notes:

1. Active duty cost share always \$0 in all points of service for all three tiers; Active duty cost share always \$0 in all points of service for all three tiers; TRICARE does not cover non-formulary medications for active duty service members unless they are determined to be medically necessary.
2. MTFs will be able to fill non-formulary requests for non-formulary medications only if both of the following conditions are met: 1) a MTF provider writes the prescription, and 2) medical necessity is established for the non-formulary medication. MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-MTF provider to whom the patient was referred, as long as medical necessity has been established.
3. Nisoldipine core coat (Sular) is now available only as a generic product. Nisoldipine geomatrix (Sular geomatrix) is a brand-only product that has the same active ingredient as the generic nisoldipine.
4. Nifedipine immediate release and Nimotop (nimodipine) are calcium channel blockers which are not typically used for the same indications or in the same patient population as other calcium channel blockers. These medications are not considered to be therapeutic alternatives to the non-formulary CCBs.

Medical Necessity Criteria for Calcium Channel Blockers

All current and new users of Calcium Channel Blockers must meet one of the following criteria in order for medical necessity to be approved:

Dihydropyridine CCBs (amlodipine, felodipine, nifedipine extended release, nisoldipine, Cardene SR, Dynacirc, Dynacirc CR, nifedipine immediate release, Sular geomatrix, nifedipine immediate release, nimodipine)

1. Use of ALL of the following formulary dihydropyridine CCBs (amlodipine, felodipine, nifedipine extended release, and nisoldipine) is contraindicated.
2. The patient has experienced significant adverse effects from ALL of the following formulary dihydropyridine CCBs (amlodipine, felodipine, nifedipine extended release, and nisoldipine).
3. The patient is stabilized on a non-formulary dihydropyridine CCB, is clinically fragile (multiple comorbidities), and

changing to a formulary dihydropyridine CCB (amlodipine, felodipine, nifedipine extended release, and nisoldipine) would incur an unacceptable risk to the patient (e.g., destabilization, abrupt worsening of symptoms).

Verapamil products (verapamil immediate release, verapamil sustained release, Verelan, Verelan PM, Covera HS)

The non-formulary cost share for a nonformulary verapamil product (Verelan, Verelan PM, or Covera HS) may be reduced to the formulary cost share if one or more of the following criteria are met:

1. Use of verapamil sustained release is contraindicated (e.g., hypersensitivity to a dye or other inert ingredient), AND treatment with Verelan, Verelan PM, or Covera HS is not contraindicated.
2. The patient is stabilized on Verelan, Verelan PM, or Covera HS, is clinically fragile (multiple comorbidities), and changing to verapamil sustained release would incur an unacceptable risk to the patient (e.g., destabilization, abrupt worsening of symptoms).

Diltiazem products (diltiazem immediate release, diltiazem sustained release, diltiazem extended release, Cardizem LA)

The non-formulary cost share for a nonformulary diltiazem product (Cardizem LA) may be reduced to the formulary cost share if one or more of the following criteria are met:

3. Use of all formulary diltiazem sustained and extended release products (including diltiazem sustained release, Diltia XT, Cartia XT, Taztia XT) is contraindicated (e.g., hypersensitivity to a dye or other inert ingredient), AND treatment with Cardizem LA is not contraindicated.
4. The patient is stabilized on Cardizem LA, is clinically fragile (multiple comorbidities), and changing to formulary diltiazem sustained or extended release products would incur an unacceptable risk of destabilization.

Criteria approved through the DoD P&T Committee process August, 2008

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TRICARE Pharmacy Program Medical Necessity Form for Dihydropyridine Calcium Channel Blockers



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This form applies to the TRICARE Pharmacy Program (TPharm). The medical necessity criteria outlined on this form also apply at Military Treatment Facilities (MTFs). The form must be completed and signed by the prescriber.

- **Amlodipine, felodipine, nifedipine, and generic nisoldipine (Sular core coat delivery system)** are the dihydropyridine calcium channel blockers (CCBs) included on the DoD Uniform Formulary. **Isradipine (immediate- and extended-release [Dynacirc CR]), nicardipine (immediate- and sustained-release [Cardene SR]), and Sular (Geomatrix delivery system)** are **non-formulary, but available to most beneficiaries at the non-formulary cost share.**
- You do **NOT** need to complete this form in order for non-active duty beneficiaries (spouses, dependents, and retirees) to obtain non-formulary medications at the non-formulary cost share. The purpose of this form is to provide information that will be used to determine if the use of a non-formulary medication *instead of a formulary medication* is medically necessary. If a non-formulary medication is determined to be medically necessary, non-active duty beneficiaries may obtain it at the formulary cost share.
- TRICARE will not cover a non-formulary medication for Active duty service members unless it is determined to be medically necessary *instead of a formulary medication*. If a non-formulary medication is determined to be medically necessary, it will be available to Active duty service members at no cost share.

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|--------------------------------------|---|------------|--|
| MAIL ORDER and RETAIL | <ul style="list-style-type: none"> The provider may call: 1-866-684-4488 or the completed form may be faxed to: 1-866-684-4477 The patient may attach the completed form to the prescription and mail it to: Express Scripts, P.O. Box 52150, Phoenix, AZ 85072-9954 or email the form only to: TpharmPA@express-scripts.com | MTF | <ul style="list-style-type: none"> Non-formulary medications are available at MTFs only if both of the following are met: <ul style="list-style-type: none"> The prescription is written by a military provider or, at the discretion of the MTF, a civilian provider to whom the patient was referred by the MTF. The non-formulary medication is determined to be medically necessary. Please contact your local MTF for more information. There are no cost shares at MTFs. |
|--------------------------------------|---|------------|--|

Step 1 Please complete patient and physician information (Please Print)

| | |
|----------------------|-----------------------|
| Patient Name: _____ | Physician Name: _____ |
| Address: _____ | Address: _____ |
| Sponsor ID #: _____ | Phone #: _____ |
| Date of Birth: _____ | Secure Fax #: _____ |

Step 2 Please explain why the patient cannot be treated with any of the formulary alternatives:
Please indicate which of the reasons below (1-4) applies to each of the formulary alternatives listed in the table. You **MUST** circle a reason AND supply a written clinical explanation specific for EACH formulary alternative.

| Formulary Alternative | Reason | Clinical Explanation |
|---|---------|----------------------|
| Amlodipine (Norvasc) | 1 2 3 4 | |
| Felodipine (Plendil) | 1 2 3 4 | |
| Nifedipine extended release (e.g., Procardia XL, Adalat CC) | 1 2 3 4 | |
| Nisoldipine core coat (Sular core coat) | 1 2 3 4 | |

1. The formulary alternative is contraindicated (e.g., due to hypersensitivity).
2. The patient has experienced significant adverse effects with the formulary alternative.
3. Use of the formulary alternative resulted in therapeutic failure.
4. The patient is stabilized on a non-formulary CCB, is clinically fragile (multiple comorbidities), and changing to a formulary alternative would incur an unacceptable risk to the patient (e.g., destabilization, abrupt worsening of symptoms).

Step 3 I certify the above is correct and accurate to the best of my knowledge. Please sign and date:

| | |
|-------------------------------|---------------|
| _____ Prescriber Signature | _____ Date |
|-------------------------------|---------------|